AE SIG – July 20, 2004

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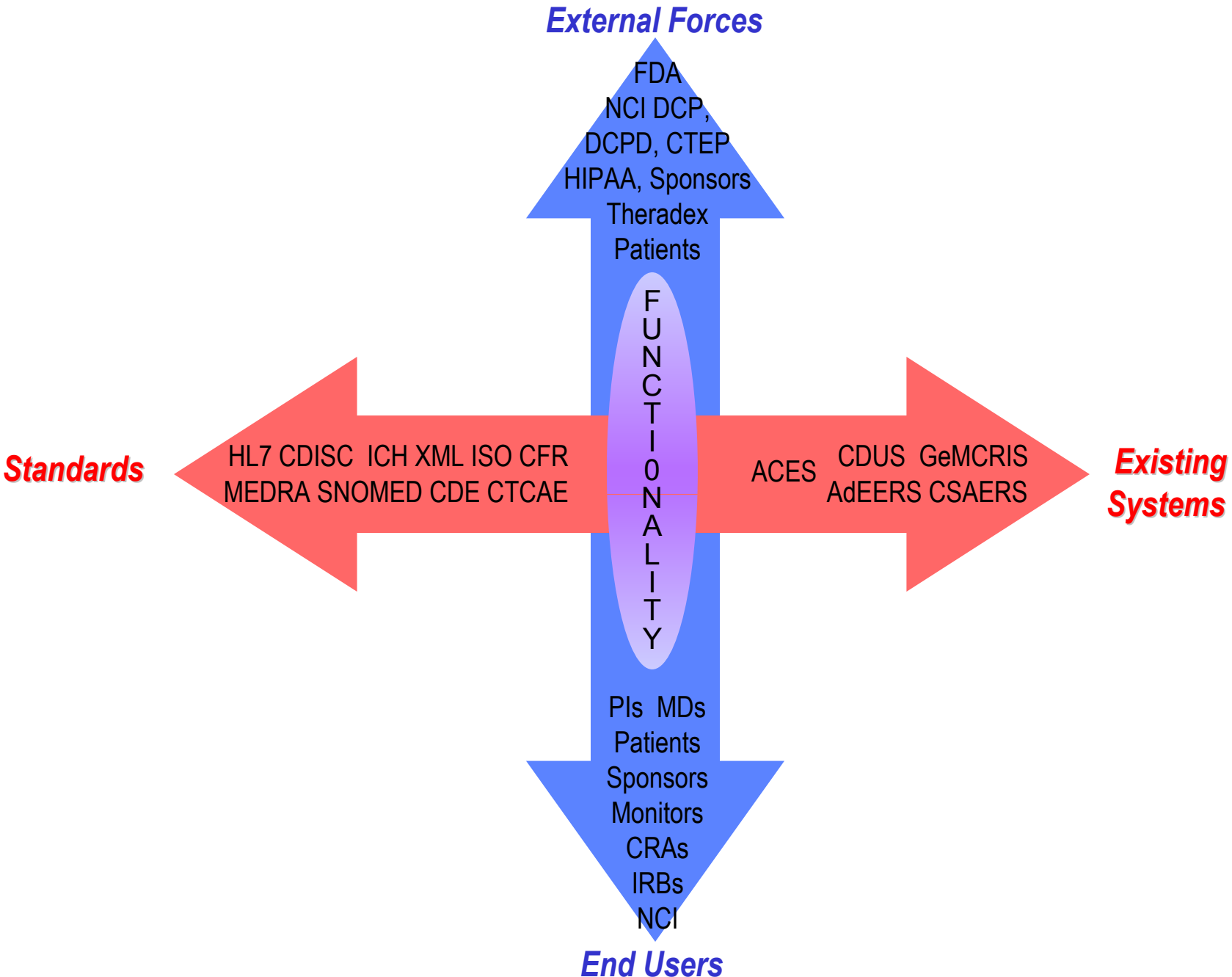
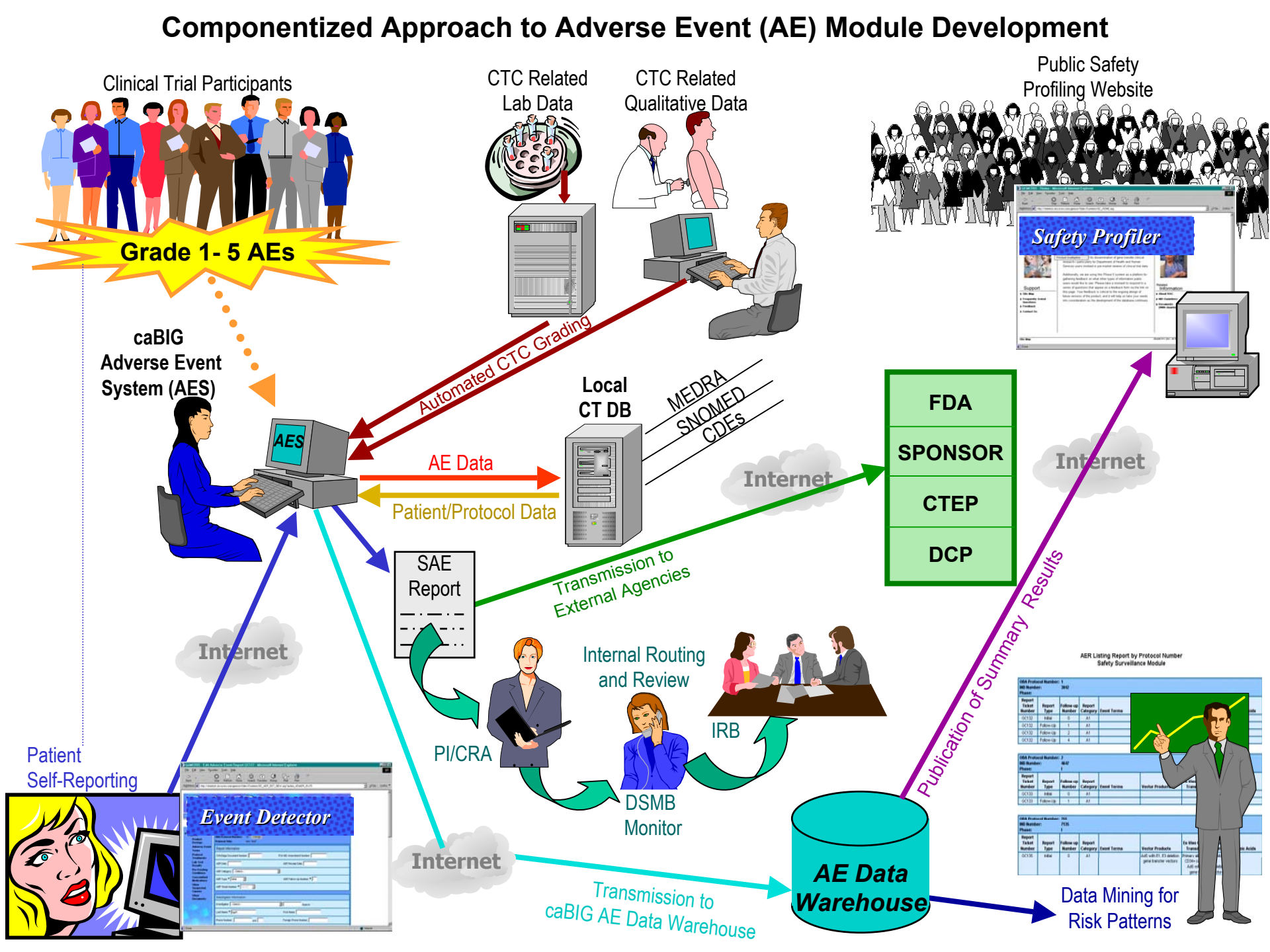
Dimensions Impacting caBIG Adverse Event (AE) Module



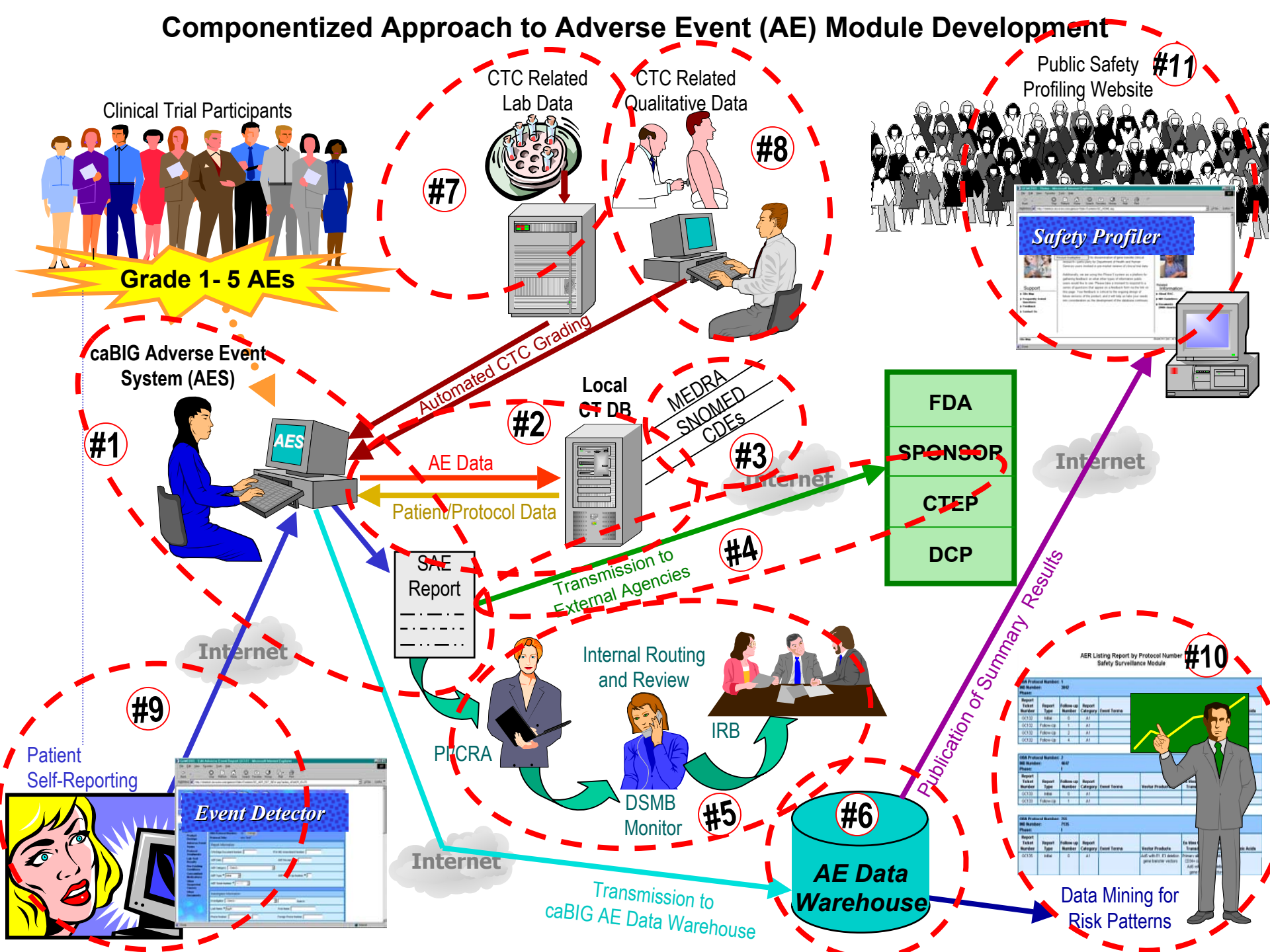
Potential Functionality of caBIG Adverse Event (AE) Module (6-18-2004)

FUNCTION	DESCRIPTION	POTENTIAL BENEFITS
Automated AE Grading	Ability to import or enter clinical data and invoke decision support to grade Adverse Events (AEs) by CTCAE criteria, for both quantitative (e.g. labs) and qualitative (e.g. clinical symptoms) data	Organize related assessments and supporting information for more efficient and effective traversal, reduce labor of chart reviews, improve efficiency of AE grading, and decrease errors
AE Data Collection	Provide capture of AE data via web-based applications and/or application-to-application messages	Provide consistent, open source solution that integrates into caBIG architecture
AE Reporting	Facilitate on-line documentation of AEs, with importing of related patient and protocol data pre-existing in other systems	Improve, standardize, and make more efficient the AE reporting process, and allow messaging and routing of AEs
Messaging of SAEs	Production of alerts when Severe Adverse Events (SAEs) occur, with immediate transmission to required agencies with verification of receipt	Expedite reporting of SAEs, decrease paper-based reports, improve MD response time and facilitate early patient intervention through alerts
Routing AEs	Ability to route AEs to appropriate parties and agencies for review, comment, and electronic signoff per a specified workflow	Reporting of AE evaluations more frequently, consistently, and efficiency, and therefore at lower cost
Integrated AE Repository	Pooled repository of evaluated AEs and modicum of related treatment and patient data for all subjects (including all subjects as denominator)	Data mining of cumulative AEs and related data to detect trends and patterns per patient, per trial, or per unit time, calculate incidence of AEs, and ensure patient safety of experimental trials
Vocabulary Management	Provide mapping among medical vocabularies when necessary, and allow customization of medical terminologies per protocol	Send messages to external groups that use different standards and meet requirements of multiple sponsors and agencies
Patient AE Self-Reporting	Web-based application to allow patients enrolled on trials to report on complications or toxicities they are experiencing, even post-trial close	Obtain real time experiential information, possibly with less bias, and more detail, and potential long-term complications otherwise undetected
Public Access to AE Information	Publish aggregated curated information on trial AEs and related data to inform clinicians and patients	Improve confidence in research and safety of trials by empowering patients and physicians to search for information and be apprised of risks

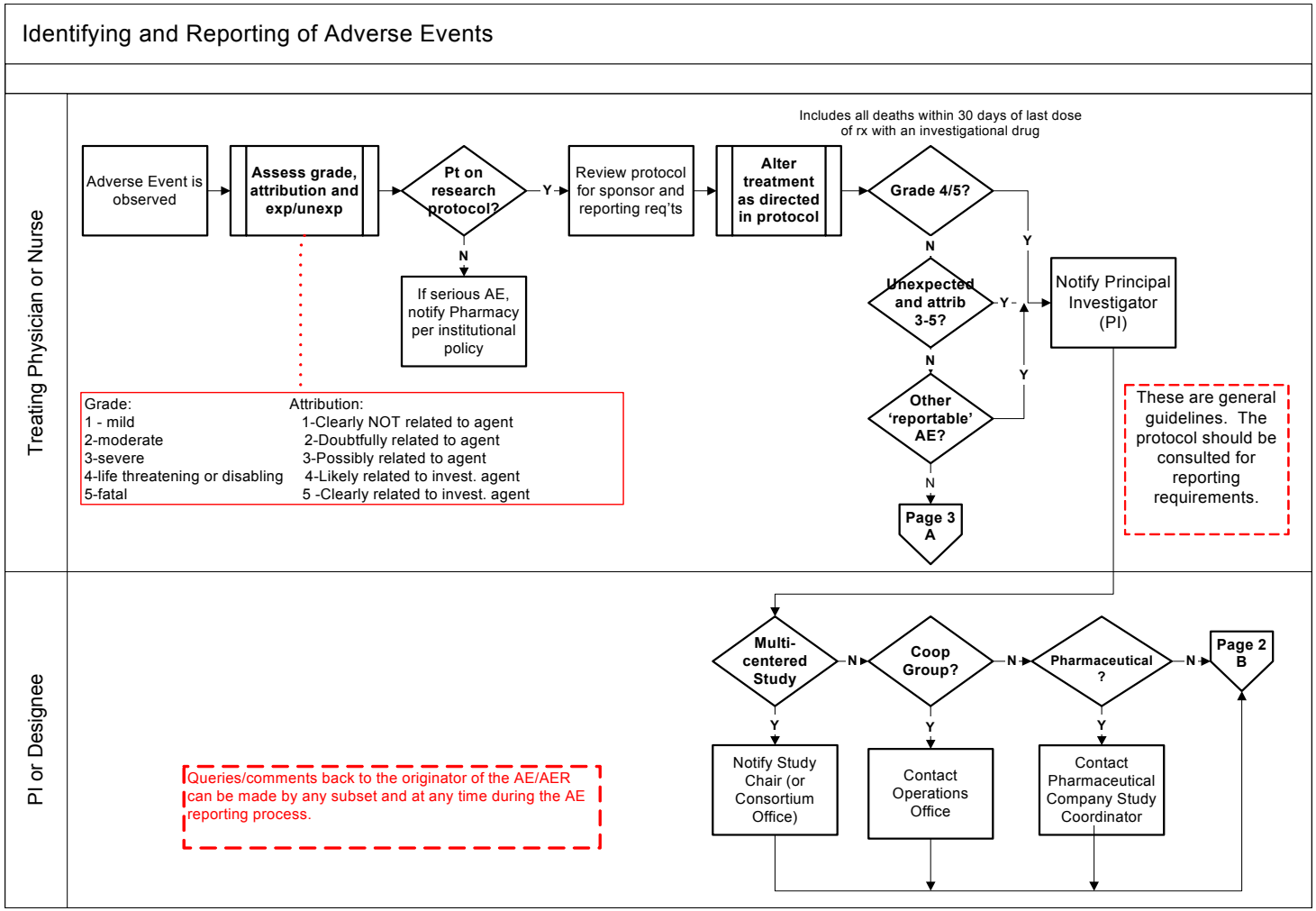
Componentized Approach to Adverse Event (AE) Module Development



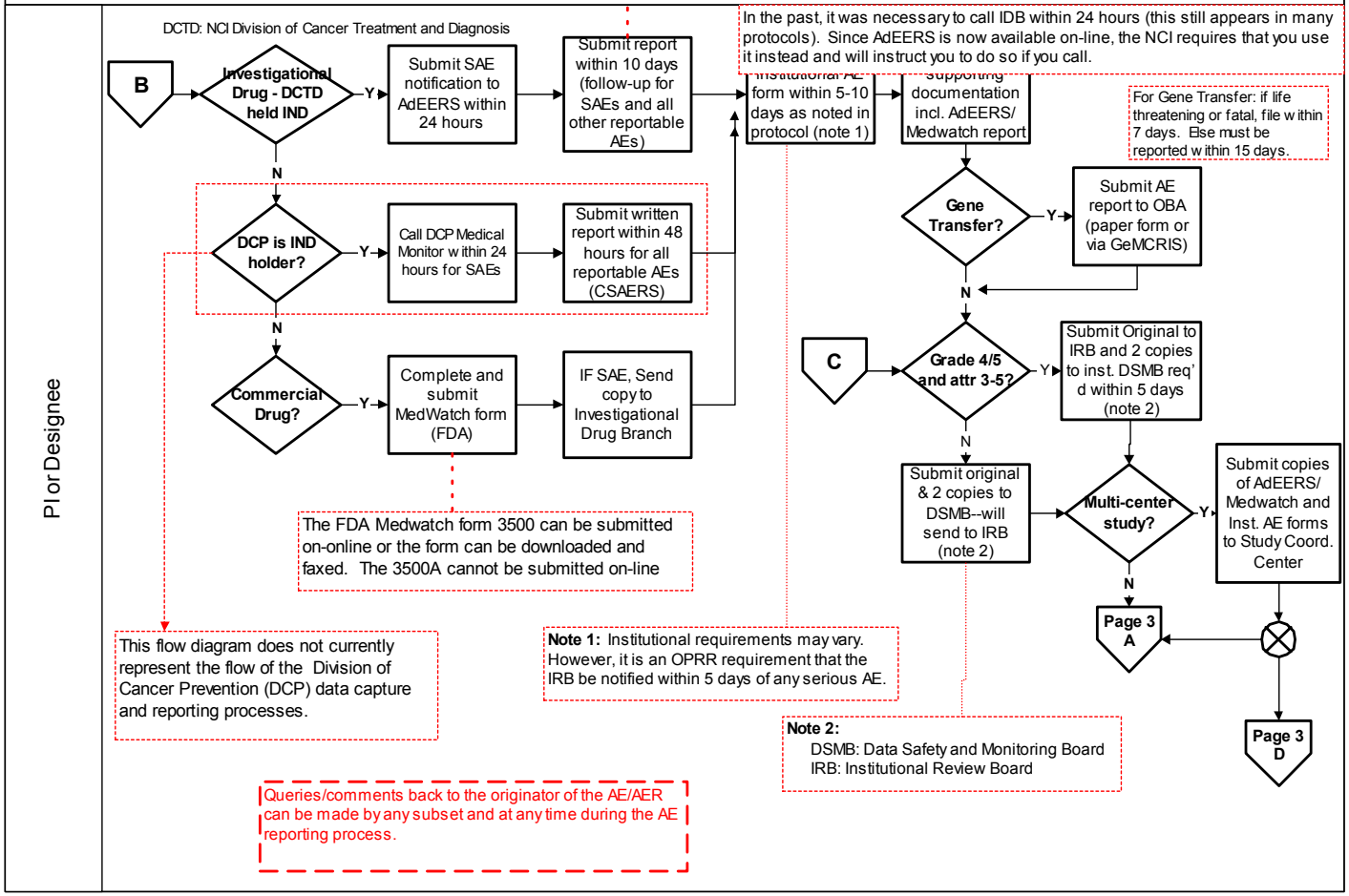
Componentized Approach to Adverse Event (AE) Module Development



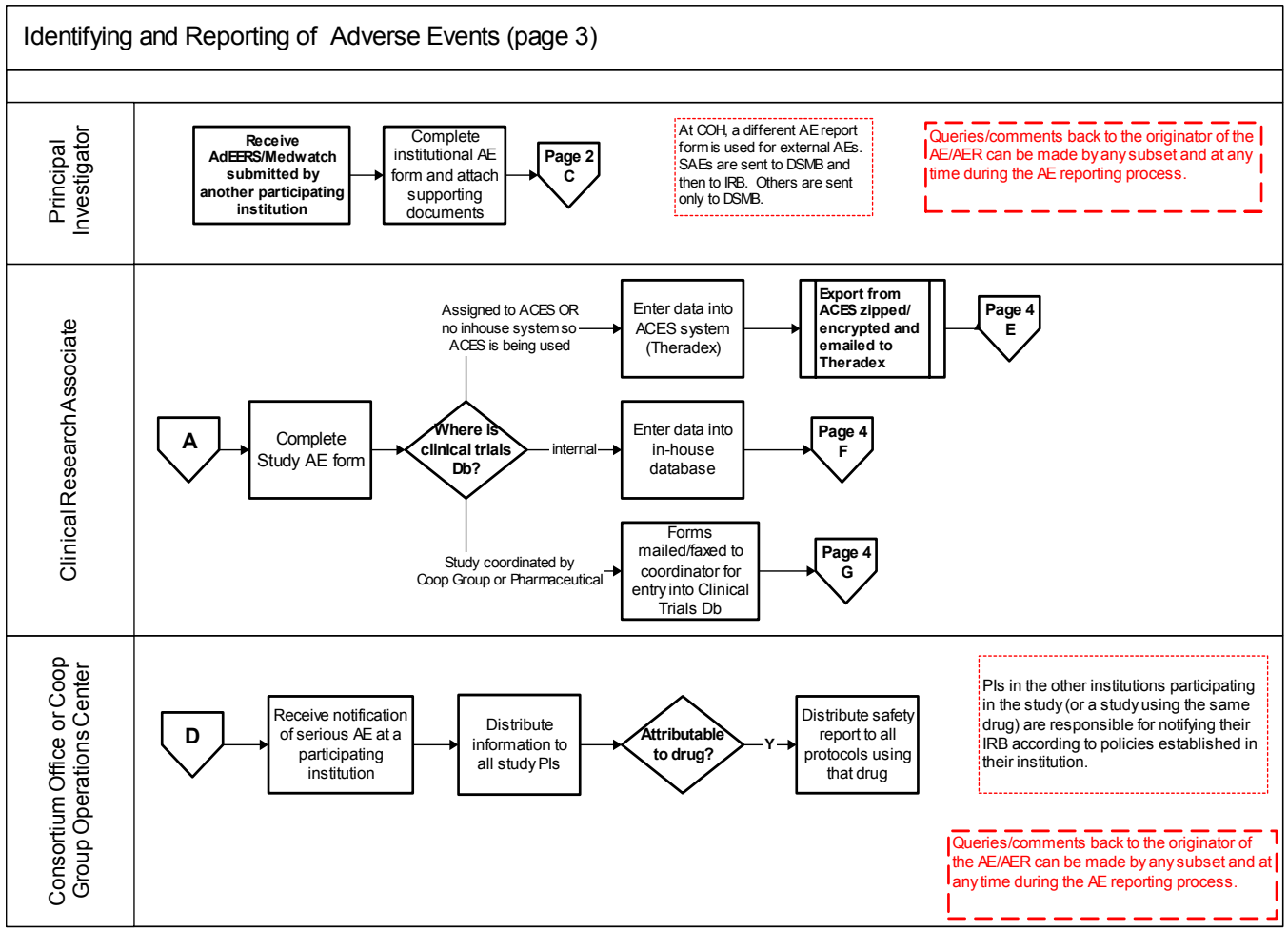
Identifying and Reporting of Adverse Events



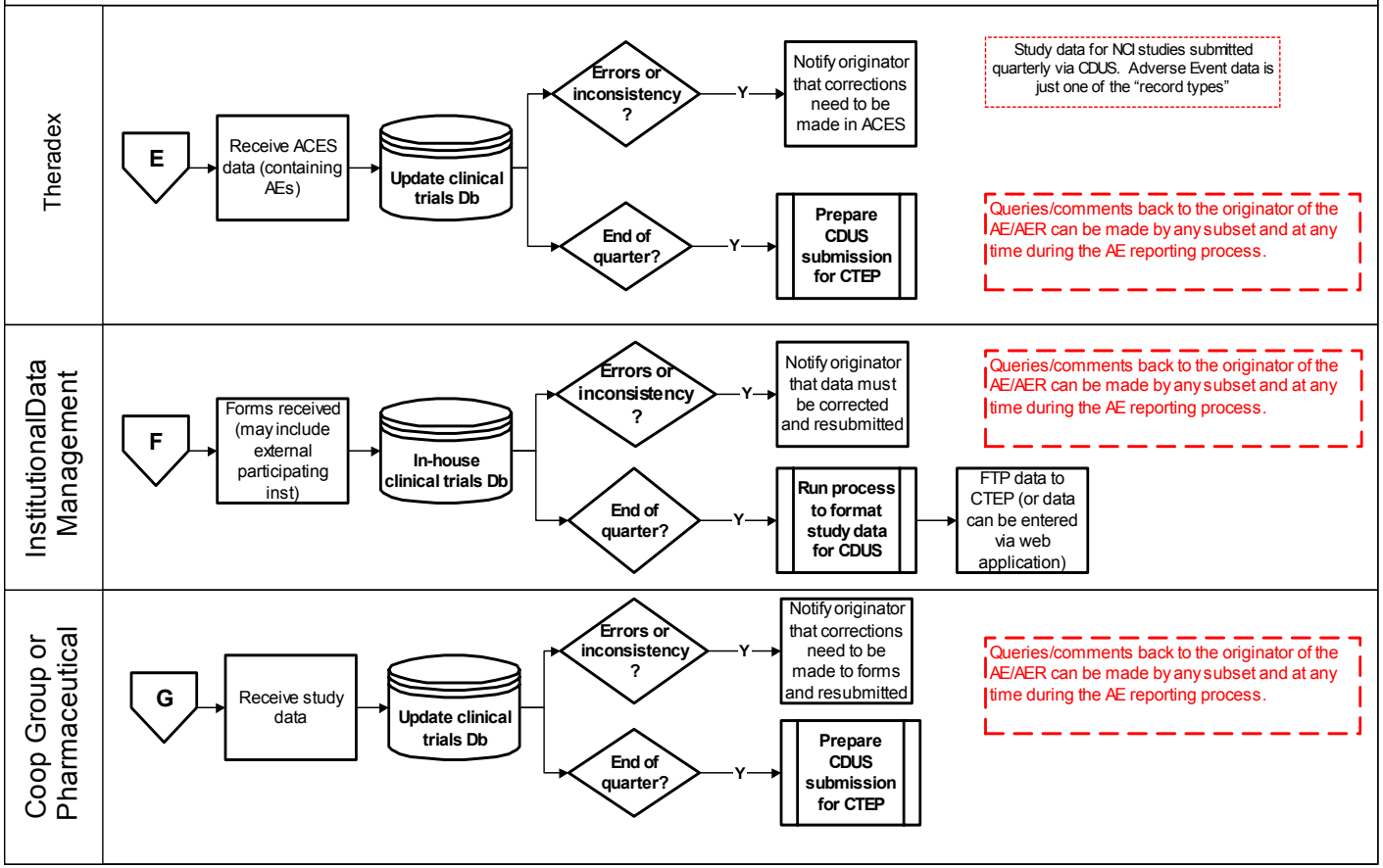
Identifying and Reporting of Adverse Events (page 2)



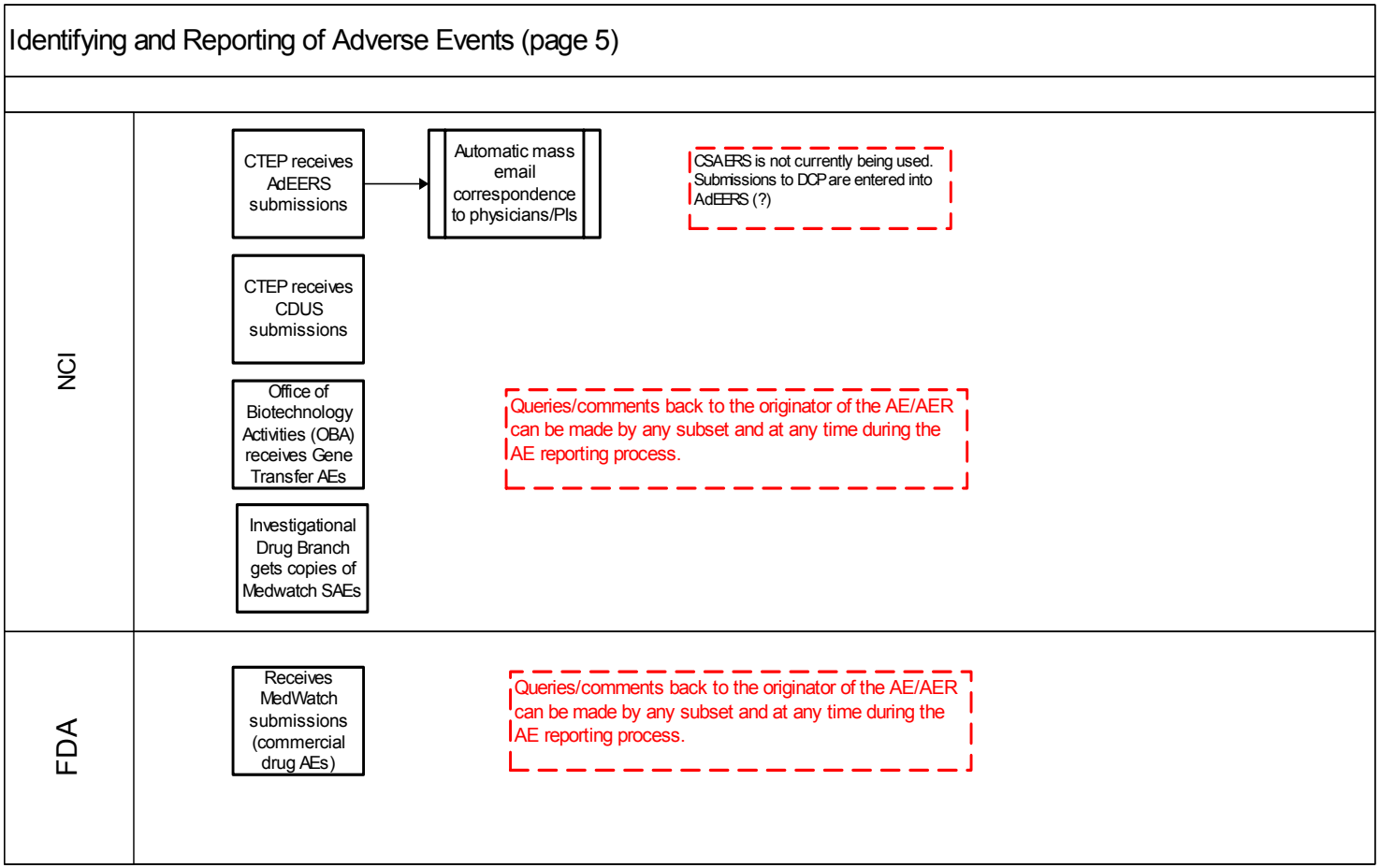
Identifying and Reporting of Adverse Events (page 3)



Identifying and Reporting of Adverse Events (page 4)



Identifying and Reporting of Adverse Events (page 5)



Action Items

- AE SIG analysis and conference call focused on HL7 Medwatch ballot
  - Recommend value domain code sets
- Get electronic changes to Activity Diagram from CTEP and complete the CTEP workflow (Ann Setser)
- Obtain rule tables from CTEP for triggering AE reporting
- Discuss SNOMED mapping issues with Vocabulary Workspace
- Follow up on MEDRA licensing issues for future AE modules (including auto-coder)
- Flowchart DCP AE information flow
- Complete domain specific vocabulary analysis, incorporating 70 attributes from Medwatch HL7 ballot
  - Incorporate co-morbidities
- Draft optimal idealized workflow for harmonized unified AE reporting module (“don’t pave the cowpath”)